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Comparative study of efficacy and safety between sublay and onlay polypropylene mesh repair for incisional hernia of abdominal wall

Meher Bhanjan

Assistant professor, Department of Surgery, Bhima Bhoi Medical College and Hospital, Balangir

Meher Sasmita

Assistant professor, Department of Pulmonary medicine, Bhima Bhoi Medical College and Hospital, Balangir

Marandi Gujaram

Assistant professor, Department of Pharmacology, Bhima Bhoi Medical College and Hospital, Balangir

Dr. Pravin. G. Dhone*

Professor & Head, Department of Pharmacology, RSDKS GMC, Ambikapur

Rai Neeta

School of Pharmacy, Vishwakarma University, Pune. Maharashtra, India

Taru Poonam

School of Pharmacy, Vishwakarma University, Pune. Maharashtra, India

Dhekale Pallavi

School of Pharmacy, Vishwakarma University, Pune. Maharashtra, India

Abstract---To compare the efficacy and safety between sublay and onlay polypropylene mesh repair for incisional hernia of abdominal wall. Department of General Surgery from January 2018 to December 2021 in BHIMA BHOI MEDICAL COLLEGE OF WESTERN ODISHA. It is a randomized controlled trial. In this study a total of 144 (72 in each group) patients were observed. The patients were randomly allocated in two groups by random method. Patients in group-A was subjected to onlay polypropylene mesh open repair procedure and patients in group-B was subjected to sublay polypropylene mesh open repair procedure for incisional hernia repair in abdominal wall. Post-operatively all patients were kept under observations for 7-10 days in surgery ward and observed for complications if any. Post-operatively

all patients were followed at 20 days, 2nd months, 6th month and 9 months to confirm the efficacy and safety of the procedure. The mean age of patients in Group-A was 30 years \pm 2.16 and 32 years \pm 3.71 in Group-B. In group-A 28 patients were male and 44 patients were female where as in group-B 27 patients were male and 45 patients were female. More over Sublay mesh repair was effective in 82% patients on the bases of recurrence while this procedure was safe in 90% cases on the bases of complications whereas onlay mesh repair was effective in 90% patients' cases on the bases of recurrence while this procedure was safe in 93% cases on the bases of complications. Onlay mesh repair technique is more effective, quick and safe as compared to sublay mesh repair technique for the treatment of incisional hernia.

Keywords---efficacy, safety, sub-lay, onlay mesh repair, incisional hernia.

Introduction

Incisional hernia, often referred to as ventral hernia, it usually occurs in the area of any prior surgical incision. These hernias usually vary in various size of defects ranging from very small to very large and sometimes complex. Incisional hernias develop in up to 2-11.5% of surgical abdominal wounds usually after open abdominal procedures. [1-3]. Incisional hernias most commonly develop due to disruption along the line of incision closure or adjacent region of suture line. Various factors like high tension placed suturing and various other factors which inhibits adequate healing such as infection, malnutrition, long smoking, various metabolic disorders and obesity. Hernial sacs containing omentum, bowel loops and pre-peritoneal fats have more chances of complications like obstruction strangulation or gangrene if the sac of the hernia is narrowed. [4-6] to prevent the recurrence of incisional hernia these are treated primarily surgical mesh repair.

Various surgical techniques for repair of incisional hernia are available among which Most popular and preferred are Mayo's, inlay, onlay and sublay mesh repair. Previously repair of incisional hernia were performed by the suture technique (Keel or Mayo's) having a higher rate of recurrence, using a simple tissue-to-tissue or suture-only technique under tension and had high recurrence rate of up to 33% after first repair and up to 44% after second repair [7] and usually within 3 years of Mayo's repair. [7,8] Previously these hernias were usually treated by tension free suture having high rate of recurrence and hence reduced its popularity in incisional hernia surgeries.[11] Suture repair is preferred nowadays when defect is less than 2 cm with a high recurrence rate up to 19% - 54% .[5,6] Incisional hernial defects larger than 2 cm in dimeters the standard treatment protocol is mesh repair.[9] Mainly three techniques of mesh repair are commonly used are onlay, sublay and inlay. As Inlay mesh repair has a tendency to create complications like chronic pain, enterocutaneous fistula formation so less frequently preferred methods. Hence in our institute we preferred onlay and sublay mesh fixing procedures.

Mesh repair has lower recurrence rate in compared to Mayo's suture repair 2.7% and 8.2%.[9] Various factors are associated with recurrence after incisional hernia repair most commonly are large seroma formation , surgical site infection, Obesity and excessive weight gain following repair .[13,14] In our institution we preferred practicing onlay polypropylene mesh fixation . The aim of our study is to compare the efficacy and safety between sublay and onlay polypropylene mesh repair for incisional hernia of abdominal wall.

Material and Methods

An Randomised Control Trial was conducted at general surgical department of Bhima Bhoi Medical College Teaching Hospital over a period of 2 years from from January 2018 to December 2021. After approval from hospital ethical committee, a total of 144 consecutive patients with incisional hernia of age between 21-70 years and both genders were admitted to surgical unit and included in the study. Patients exclusion criteria are age group above 70 years, incisional hernial defect size less than 2 cm, recurrent incisional hernia, obstructed/strangulated hernias, hernias other than incisional hernia, patients having COPD and chronic liver, renal or cardiac impairment were excluded from the study. Total patients were selected through nonprobability consecutive technique. After taking informed and written consent of the patients and relatives, detailed history and thorough examination and relevant investigations of were done. Exclusion criteria strictly followed to reduce the study Bias. By lottery the patients were allocated in two groups randomly.

Patients in group-A was subjected to Onlay mesh repair procedure and patients in group-B was subjected to sublay mesh repair procedure for incisional hernia repair without being informed about the type of procedure to the patients or attendant. The respective mesh repair procedure (onlay mesh repair for group-A and sublay mesh repair for group-B) was applied to patients of relevant group. Post-operatively all patients were kept under observations in our surgical unit for 10 days and drain and stiches removed on 10th day. Observation made for complications like seroma formation, hematoma and surgical site infection. Post-operatively all patients were followed at 20 days, 2nd month ,6 months and 9 months to confirm efficacy and safety of the procedure. All the data was recorded on a standardized proforma. Bias and confounders in the study were controlled by strictly following the exclusion criteria. The data was analysed with the help of computer software SPSS for windows version 16.0. Frequencies and percentages were calculated for categorical variables like gender, efficacy and safety. Mean± SD was calculated for numerical variables like age. Chi-Square test was used to compare the efficacy and safety in both the groups. P value of < 0.05 was considered significant. Efficacy and safety in both groups was stratified among the age and gender to see the effect modifiers. All the results were presented as tables and charts.

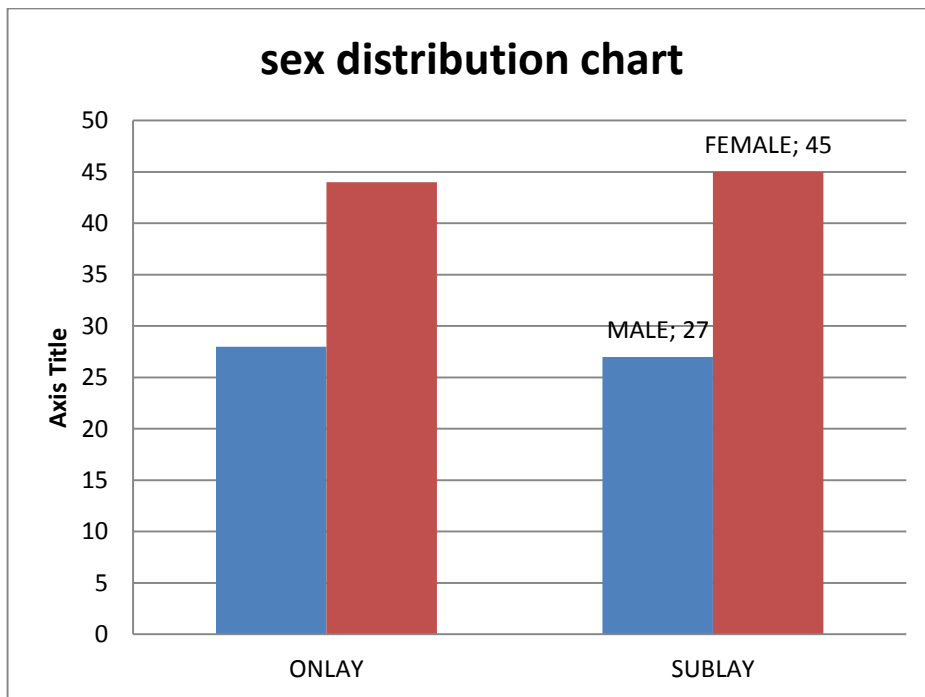
Results

In this study sex distribution among two groups total 55 male undergone surgery, among which 28 prefer ONLAY and 27 SUBLAY. In Female group total 89 were there, among them 44 ONLAY and 45 PREFER SUBLAY. When we consider the

age distribution age group 31 to 40 having maximum number and preferring surgery, SUBLAY is more preferable, least preferable group is >60 and stable vital is important before any surgery. When we consider safety profile, both surgeries are safety but ONLAY is more preferable than SUBLAY. When we consider the complication part, SUBLAY procedure having maximum complication than ONLAY part.

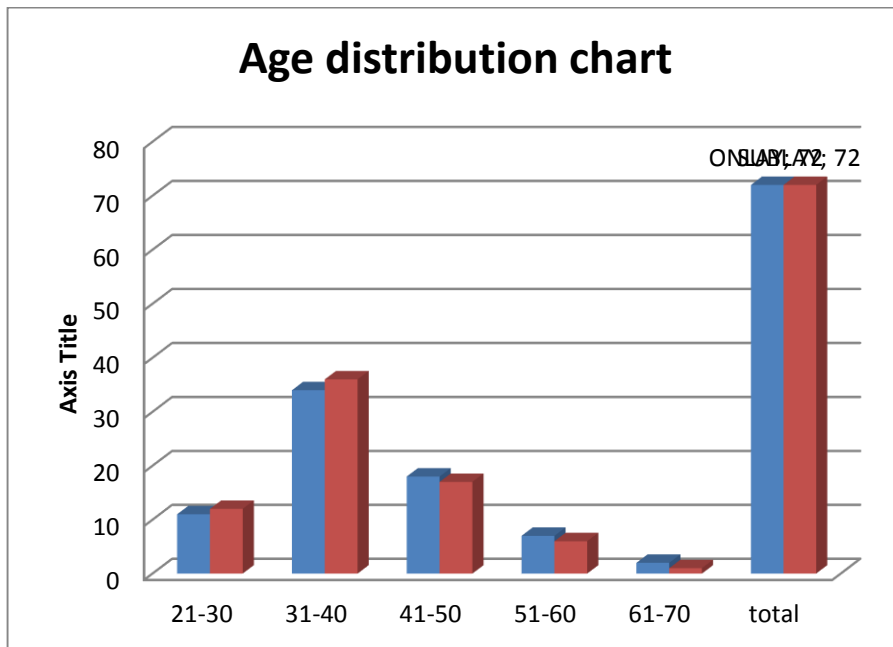
SEX Distribution

Sex	Onlay	Sublay
Male	28	27
Female	44	45



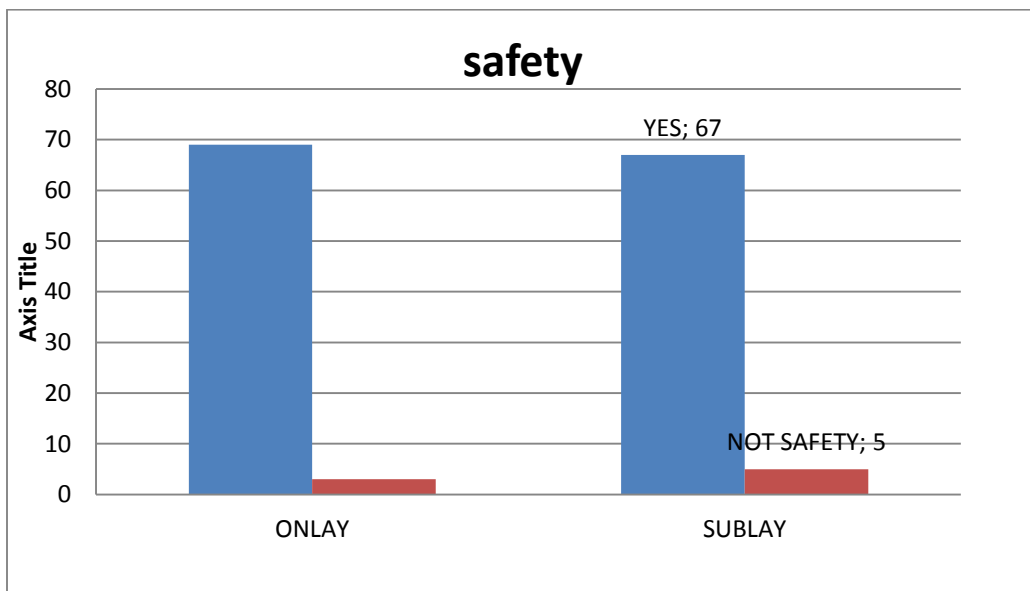
Age Distribution

Age	Onlay	Sublay
21-30	11	12
31-40	34	36
41-50	18	17
51-60	7	6
61-70	2	1
Total	72	72



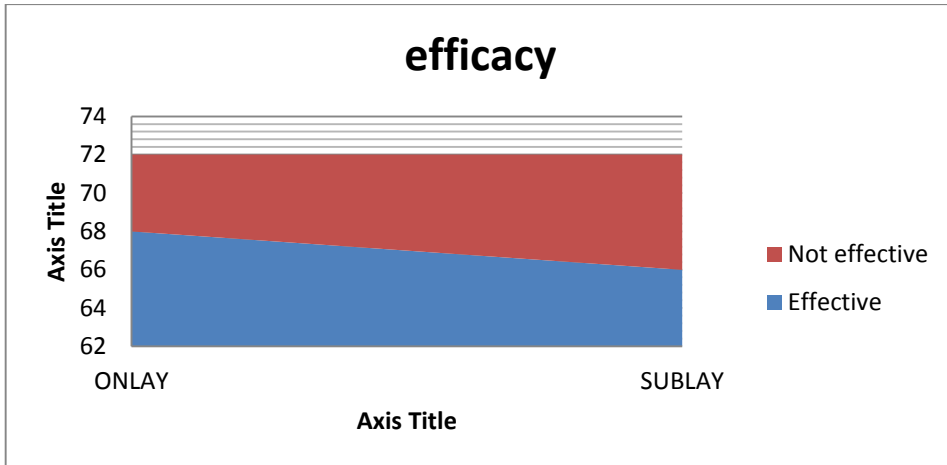
Safety

	Safety	Onlay	Sublay
Yes		69	67
Not Safety		3	5



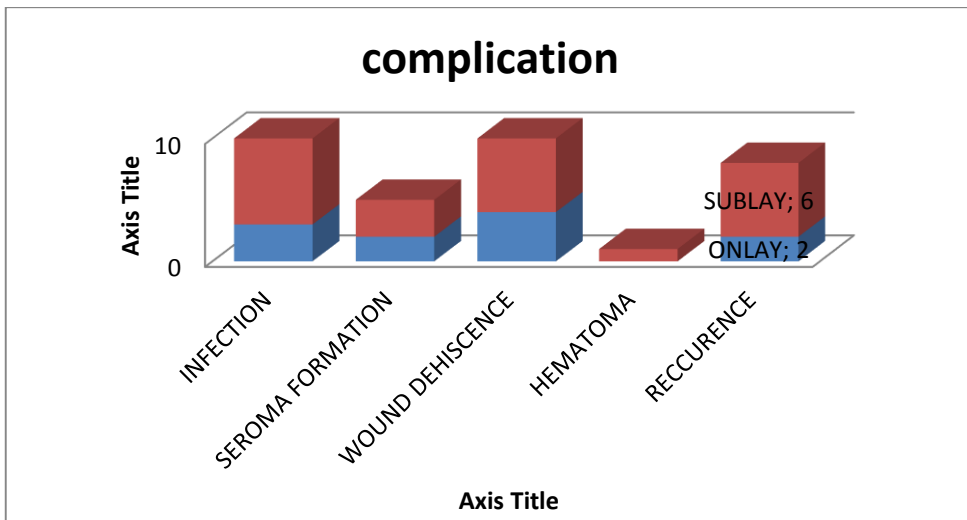
Efficacy

Efficacy	Onlay	Sublay
Effective	68	66
Not Effective	4	6



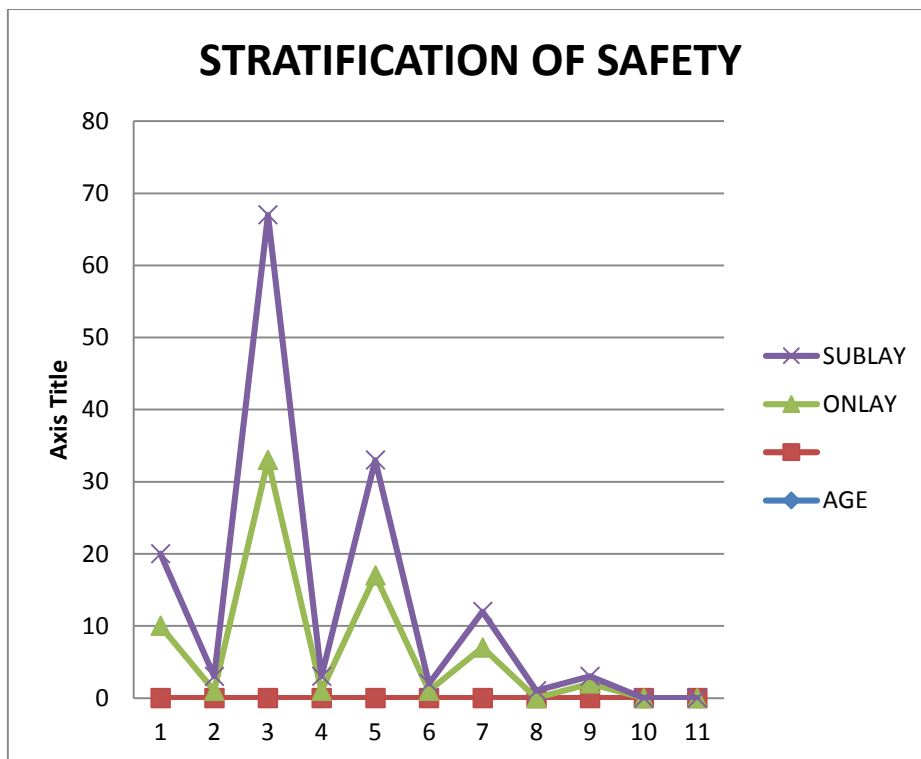
Complication

Complications	Onlay	Sublay
Infection	3	7
Seroma formation	2	3
Wound dehiscence	4	6
Hematoma	0	1
Reccurence	2	6



Stratification of safety with respect to age and sex

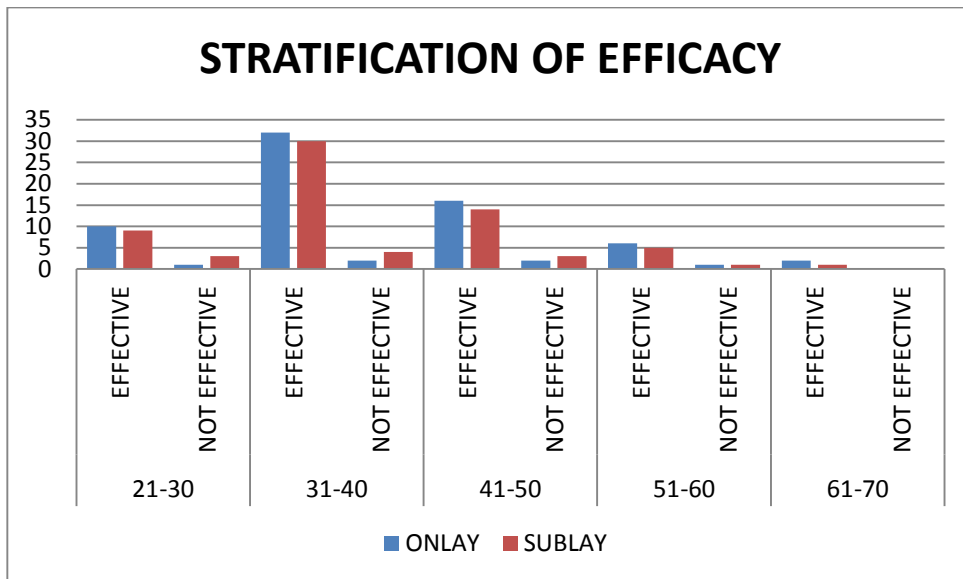
Age		Onlay	Sublay
21-30	Safe	10	10
	Unsafe	1	2
31-40	Safe	33	34
	Unsafe	1	2
41-50	Safe	17	16
	Unsafe	1	1
51-60	Safe	7	5
	Unsafe	0	1
61-70	Safe	2	1
	Unsafe	0	0



Stratification of Efficacy with Respect to Age Sex

Age		Onlay	Sublay
21-30	Effective	10	9
	Not effective	1	3
31-40	Effective	32	30
	Not effective	2	4
41-50	Effective	16	14
	Not effective	2	3
51-60	Effective	6	5

	Not effective	1	1
61-70	Effective	2	1
	Not effective	0	0



In age range 41-50 years, 8(13%) were in age range 51-65 years. Mean age was 30 years with standard deviation ± 2.16 in group-B. In group -A 13 (20%) patients were in age range 21-30 years, 22 (35%) were in age range 31-40 years and 19 (30%) were in age range 41-50 years, 9 (15%) were in age range 51-65 years. Mean age was 32-years with standard deviation ± 3.71 as shown in table-1. Gender distribution among two groups was analysed as in group-A 30 (48%) patients were male and 33(52%) patients were female where as in group-B 28 (45%) patients were male and 35 (55%) patients were female as shown in table- 2. Complication between two groups was analysed as in group-A 3(5%) patients had seroma, 4(6%) patients had hematoma and 6(10%) patients had wound infection while the recurrence rate was 11(18%) where as in group-B 2 (3%) patients had seroma, 1(2%) patients had hematoma and 4(7%) patients had wound infection while the recurrence rate was 6(10%) as shown in table-3. Efficacy and safety of two groups was analysed as group-A (Sublay mesh repair) was effective in 52(82%) patients on the bases of recurrence while this procedure was safe in 57 (90%) cases on the bases of complications whereas group B (onlay mesh repair) was effective in 57 (90%) patients cases on the bases of recurrence while this procedure was safe in 59 (93%) cases on the bases of complications as shown in table-4 and 5. Stratification of efficacy and safety with respect to age and gender is given in table no 6,7,8,9.

Discussion

Ventral hernia in the anterior abdominal wall includes both spontaneous and, most commonly, incisional hernias after an abdominal operation. It is estimated that 2 to 10% of all abdominal operations result in an incisional hernia. Small

hernias less than 2 ½ cm in diameter are often successfully closed with primary tissue repairs.

However, larger ones have a recurrence rate of up to 30-40% when a tissue repair alone is performed.^{7,8} Hernia recurrence is distressing to patient and embarrassing to surgeons. Now-a-days tension free repair using prosthetic mesh has decreased recurrence to negligible. Despite excellent results increased risk of infection with placement of a foreign body and cost factor still exist; however, operating time and hospital length of stay are shortened. Primary tissue repair is associated with higher unacceptable recurrence rate, now-a-days; tension free mesh repair is ideal hernia repair technique.^[9] Our study shows that in onlay mesh repair 3% patients had seroma, 2% patients had hematoma and 7% patients had wound infection while the recurrence rate was 10%. Where as in sublay group 5% patients had seroma, 6% patients had hematoma and 10% patients had wound infection while the recurrence rate was 18%.

Similar results were cited by Winker MS et al in which complication in onlay mesh repair 5% patients had seroma, 3% patients had hematoma and 12% patients had wound infection while the recurrence rate was 13%. Where as in sublay group 7% patients had seroma, 8% patients had hematoma and 20% patients had wound infection while the recurrence rate was 20%.^[10] Our results show that onlay mesh repair was effective in 90% patients and was not effective in 10% cases on the bases of recurrence while this procedure was safe in 93% cases on the bases of complications. On the other hand, sublay mesh repair was effective in 82% patients and was not effective in 18% cases on the bases of recurrence while this procedure was safe in 90% cases on the bases of complications.

Similar results were observed in study done by Weber G et al and Godara R et al as onlay mesh repair was effective in 88% patients and was not effective in 12% cases on the bases of recurrence while this procedure was safe in 87% cases on the bases of complications. On the other hand, sublay mesh repair was effective in 80% patients and was not effective in 20% cases on the bases of recurrence while this procedure was safe in 81% cases on the bases of complications. ^[10,11]

The mean total time taken for the operation in “sublay” groups was 63.15 ± 15.0 mins compared with 49.35 ± 8.29 mins in ‘Onlay’ group and was found to be statistically significant (P<0.05) suggesting that fair degree of experience, meticulousness and gentleness of sublay or onlay placement should be equal in terms of skill.

Apart from recurrence other post-operative complications like seroma formation, hematoma, cellulitis, wound infection attributed largely to extensive dissection and tissue handling during hernia repair. In our study no significant difference in these complications in either group was found except that there were slightly more chances of seroma formation in sublay groups which may be due to extensive tissue dissection and increased blood loss. Duration of hospital stay give us an indirect indication of degree of morbidity in terms of post-operative complication. The mean duration in sublay groups was 6.8 days compared to 4.6 days in onlay group and were found to be statistically significant (p< 0.05). On two year follow up no recurrence was found in either group, similar results were

also observed by others. In fact as per literature, the best position for inserting the material has not been conclusively established; but limited studies have shown that meshes implanted on the abdominal aponeurotic layer showed better and early incorporation (higher collagen deposition, capillary density and cell accumulation) and increased tensile strength reflecting tighter anchorage to the abdominal wall.[12,13]

One European study has shown that onlay technique had significantly more complications as compared to other technique but we have not found such results in our study.[14-16] Thus it can be safely said that based on above parameters onlay is a better technique than sublay in terms of placement & overall convenience. There is paucity of literature but an experimental study has also shown superiority of onlay technique based on different parameters. However, in few studies it was found that ideal position for mesh repair appears to be retro muscular, where the force of abdominal pressure holds the prosthesis against deep surfaces of muscles.[16] Even after long term follow up, recurrence rates around 10% are possible. [7,17,18]. This is all the more necessary as the world literature is scanty and there is great interest in hernia surgery using mesh these days.

Conclusion

Our study concludes that onlay mesh repair technique was more effective, quick and safe as compared to sublay mesh repair technique for the treatment of para-umbilical hernia

Conflict of interest: none

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